

AMENDED IN ASSEMBLY MARCH 18, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2679**

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**Introduced by Assembly Member Cooley**

February 19, 2016

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An act to amend Section 19353 of the Business and Professions Code, *and to amend Section 11362.9 of the Health and Safety Code*, relating to medical marijuana.

LEGISLATIVE COUNSEL’S DIGEST

AB 2679, as amended, Cooley. Medical-~~marijuana~~. *marijuana: regulation: research.*

Existing law, the Medical Marijuana Regulation and Safety Act, provides for the licensure of persons engaged in specified activities relating to medical marijuana and establishes other regulatory provisions. That act also requires each licensing authority to prepare and submit to the Legislature an annual report on the authority’s activities and post the report on the authority’s Internet Web site.

This bill would ~~make a nonsubstantive change to that provision:~~ *require the report to also include the number of appeals from the denial of state licenses or other disciplinary actions taken by the licensing authority, the average time spent on these appeals, and the number of complaints submitted by citizens or representatives of cities or counties regarding licensees, as specified.*

*Existing law authorizes the creation by the University of California of the California Marijuana Research Program, the purpose of which is to develop and conduct studies intended to ascertain the general medical safety and efficacy of marijuana, and if found valuable, to*

*develop medical guidelines for the appropriate administration and use of marijuana.*

*This bill would specify that the studies may include studies to ascertain the effect of marijuana on motor skills.*

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 19353 of the Business and Professions  
2 Code is amended to read:  
3 19353. Beginning on March 1, 2023, and on or before March  
4 1 of each year thereafter, each licensing authority shall prepare  
5 and submit to the Legislature an annual report on the authority's  
6 ~~activities~~ *activities, in compliance with Section 9795 of the*  
7 *Government Code*, and post the report on the authority's Internet  
8 Web site. The report shall include, but not be limited to, the  
9 following information for the previous fiscal year:  
10 (a) The amount of funds allocated and spent by the licensing  
11 authority for medical cannabis licensing, enforcement, and  
12 administration.  
13 (b) The number of state licenses issued, renewed, denied,  
14 suspended, and revoked, by state license category.  
15 (c) The average time for processing state license applications,  
16 by state license category.  
17 (d) *The number of appeals from the denial of state licenses or*  
18 *other disciplinary actions taken by the licensing authority and the*  
19 *average time spent on these appeals.*  
20 (e) *The number of complaints submitted by citizens or*  
21 *representatives of cities or counties regarding licensees, provided*  
22 *as both a comprehensive statewide number and by geographical*  
23 *region.*  
24 ~~(d)~~  
25 (f) The number and type of enforcement activities conducted  
26 by the licensing authorities and by local law enforcement agencies  
27 in conjunction with the licensing authorities or the bureau.  
28 ~~(e)~~  
29 (g) The number, type, and amount of penalties, fines, and other  
30 disciplinary actions taken by the licensing authorities.

1     SEC. 2. Section 11362.9 of the Health and Safety Code is  
2     amended to read:

3     11362.9. (a) (1) It is the intent of the Legislature that the state  
4     commission objective scientific research by the premier research  
5     institute of the world, the University of California, regarding the  
6     efficacy and safety of administering marijuana as part of medical  
7     treatment. If the Regents of the University of California, by  
8     appropriate resolution, accept this responsibility, the University  
9     of California shall create a program, to be known as the California  
10    Marijuana Research Program.

11    (2) The program shall develop and conduct studies intended to  
12    ascertain the general medical safety and efficacy of marijuana and,  
13    if found valuable, shall develop medical guidelines for the  
14    appropriate administration and use of marijuana. *The studies may*  
15    *include studies to ascertain the effect of marijuana on motor skills.*

16    (b) The program may immediately solicit proposals for research  
17    projects to be included in the marijuana studies. Program  
18    requirements to be used when evaluating responses to its  
19    solicitation for proposals, shall include, but not be limited to, all  
20    of the following:

21    (1) Proposals shall demonstrate the use of key personnel,  
22    including clinicians or scientists and support personnel, who are  
23    prepared to develop a program of research regarding marijuana's  
24    general medical efficacy and safety.

25    (2) Proposals shall contain procedures for outreach to patients  
26    with various medical conditions who may be suitable participants  
27    in research on marijuana.

28    (3) Proposals shall contain provisions for a patient registry.

29    (4) Proposals shall contain provisions for an information system  
30    that is designed to record information about possible study  
31    participants, investigators, and clinicians, and deposit and analyze  
32    data that accrues as part of clinical trials.

33    (5) Proposals shall contain protocols suitable for research on  
34    marijuana, addressing patients diagnosed with the acquired  
35    immunodeficiency syndrome (AIDS) or the human  
36    immunodeficiency virus (HIV), cancer, glaucoma, or seizures or  
37    muscle spasms associated with a chronic, debilitating condition.  
38    The proposal may also include research on other serious illnesses,  
39    provided that resources are available and medical information  
40    justifies the research.

1 (6) Proposals shall demonstrate the use of a specimen laboratory  
2 capable of housing plasma, urine, and other specimens necessary  
3 to study the concentration of cannabinoids in various tissues, as  
4 well as housing specimens for studies of toxic effects of marijuana.

5 (7) Proposals shall demonstrate the use of a laboratory capable  
6 of analyzing marijuana, provided to the program under this section,  
7 for purity and cannabinoid content and the capacity to detect  
8 contaminants.

9 (c) In order to ensure objectivity in evaluating proposals, the  
10 program shall use a peer review process that is modeled on the  
11 process used by the National Institutes of Health, and that guards  
12 against funding research that is biased in favor of or against  
13 particular outcomes. Peer reviewers shall be selected for their  
14 expertise in the scientific substance and methods of the proposed  
15 research, and their lack of bias or conflict of interest regarding the  
16 applicants or the topic of an approach taken in the proposed  
17 research. Peer reviewers shall judge research proposals on several  
18 criteria, foremost among which shall be both of the following:

19 (1) The scientific merit of the research plan, including whether  
20 the research design and experimental procedures are potentially  
21 biased for or against a particular outcome.

22 (2) Researchers' expertise in the scientific substance and  
23 methods of the proposed research, and their lack of bias or conflict  
24 of interest regarding the topic of, and the approach taken in, the  
25 proposed research.

26 (d) If the program is administered by the Regents of the  
27 University of California, any grant research proposals approved  
28 by the program shall also require review and approval by the  
29 research advisory panel.

30 (e) It is the intent of the Legislature that the program be  
31 established as follows:

32 (1) The program shall be located at one or more University of  
33 California campuses that have a core of faculty experienced in  
34 organizing multidisciplinary scientific endeavors and, in particular,  
35 strong experience in clinical trials involving psychopharmacologic  
36 agents. The campuses at which research under the auspices of the  
37 program is to take place shall accommodate the administrative  
38 offices, including the director of the program, as well as a data  
39 management unit, and facilities for storage of specimens.

1 (2) When awarding grants under this section, the program shall  
2 utilize principles and parameters of the other well-tested statewide  
3 research programs administered by the University of California,  
4 modeled after programs administered by the National Institutes of  
5 Health, including peer review evaluation of the scientific merit of  
6 applications.

7 (3) The scientific and clinical operations of the program shall  
8 occur, partly at University of California campuses, and partly at  
9 other postsecondary institutions, that have clinicians or scientists  
10 with expertise to conduct the required studies. Criteria for selection  
11 of research locations shall include the elements listed in subdivision  
12 (b) and, additionally, shall give particular weight to the  
13 organizational plan, leadership qualities of the program director,  
14 and plans to involve investigators and patient populations from  
15 multiple sites.

16 (4) The funds received by the program shall be allocated to  
17 various research studies in accordance with a scientific plan  
18 developed by the Scientific Advisory Council. As the first wave  
19 of studies is completed, it is anticipated that the program will  
20 receive requests for funding of additional studies. These requests  
21 shall be reviewed by the Scientific Advisory Council.

22 (5) The size, scope, and number of studies funded shall be  
23 commensurate with the amount of appropriated and available  
24 program funding.

25 (f) All personnel involved in implementing approved proposals  
26 shall be authorized as required by Section 11604.

27 (g) Studies conducted pursuant to this section shall include the  
28 greatest amount of new scientific research possible on the medical  
29 uses of, and medical hazards associated with, marijuana. The  
30 program shall consult with the Research Advisory Panel analogous  
31 agencies in other states, and appropriate federal agencies in an  
32 attempt to avoid duplicative research and the wasting of research  
33 dollars.

34 (h) The program shall make every effort to recruit qualified  
35 patients and qualified physicians from throughout the state.

36 (i) The marijuana studies shall employ state-of-the-art research  
37 methodologies.

38 (j) The program shall ensure that all marijuana used in the  
39 studies is of the appropriate medical quality and shall be obtained  
40 from the National Institute on Drug Abuse or any other federal

1 agency designated to supply marijuana for authorized research. If  
2 these federal agencies fail to provide a supply of adequate quality  
3 and quantity within six months of the effective date of this section,  
4 the Attorney General shall provide an adequate supply pursuant  
5 to Section 11478.

6 (k) The program may review, approve, or incorporate studies  
7 and research by independent groups presenting scientifically valid  
8 protocols for medical research, regardless of whether the areas of  
9 study are being researched by the committee.

10 (l) (1) To enhance understanding of the efficacy and adverse  
11 effects of marijuana as a pharmacological agent, the program shall  
12 conduct focused controlled clinical trials on the usefulness of  
13 marijuana in patients diagnosed with AIDS or HIV, cancer,  
14 glaucoma, or seizures or muscle spasms associated with a chronic,  
15 debilitating condition. The program may add research on other  
16 serious illnesses, provided that resources are available and medical  
17 information justifies the research. The studies shall focus on  
18 comparisons of both the efficacy and safety of methods of  
19 administering the drug to patients, including inhalational, tinctural,  
20 and oral, evaluate possible uses of marijuana as a primary or  
21 adjunctive treatment, and develop further information on optimal  
22 dosage, timing, mode of administration, and variations in the effects  
23 of different cannabinoids and varieties of marijuana.

24 (2) The program shall examine the safety of marijuana in  
25 patients with various medical disorders, including marijuana's  
26 interaction with other drugs, relative safety of inhalation versus  
27 oral forms, and the effects on mental function in medically ill  
28 persons.

29 (3) The program shall be limited to providing for objective  
30 scientific research to ascertain the efficacy and safety of marijuana  
31 as part of medical treatment, and should not be construed as  
32 encouraging or sanctioning the social or recreational use of  
33 marijuana.

34 (m) (1) Subject to paragraph (2), the program shall, prior to  
35 any approving proposals, seek to obtain research protocol  
36 guidelines from the National Institutes of Health and shall, if the  
37 National Institutes of Health issues research protocol guidelines,  
38 comply with those guidelines.

39 (2) If, after a reasonable period of time of not less than six  
40 months and not more than a year has elapsed from the date the

1 program seeks to obtain guidelines pursuant to paragraph (1), no  
2 guidelines have been approved, the program may proceed using  
3 the research protocol guidelines it develops.

4 (n) In order to maximize the scope and size of the marijuana  
5 studies, the program may do any of the following:

6 (1) Solicit, apply for, and accept funds from foundations, private  
7 individuals, and all other funding sources that can be used to  
8 expand the scope or timeframe of the marijuana studies that are  
9 authorized under this section. The program shall not expend more  
10 than 5 percent of its General Fund allocation in efforts to obtain  
11 money from outside sources.

12 (2) Include within the scope of the marijuana studies other  
13 marijuana research projects that are independently funded and that  
14 meet the requirements set forth in subdivisions (a) to (c), inclusive.  
15 In no case shall the program accept any funds that are offered with  
16 any conditions other than that the funds be used to study the  
17 efficacy and safety of marijuana as part of medical treatment. Any  
18 donor shall be advised that funds given for purposes of this section  
19 will be used to study both the possible benefits and detriments of  
20 marijuana and that he or she will have no control over the use of  
21 these funds.

22 (o) (1) Within six months of the effective date of this section,  
23 the program shall report to the Legislature, the Governor, and the  
24 Attorney General on the progress of the marijuana studies.

25 (2) Thereafter, the program shall issue a report to the Legislature  
26 every six months detailing the progress of the studies. The interim  
27 reports required under this paragraph shall include, but not be  
28 limited to, data on all of the following:

29 (A) The names and number of diseases or conditions under  
30 study.

31 (B) The number of patients enrolled in each study by disease.

32 (C) Any scientifically valid preliminary findings.

33 (p) If the Regents of the University of California implement  
34 this section, the President of the University of California shall  
35 appoint a multidisciplinary Scientific Advisory Council, not to  
36 exceed 15 members, to provide policy guidance in the creation  
37 and implementation of the program. Members shall be chosen on  
38 the basis of scientific expertise. Members of the council shall serve  
39 on a voluntary basis, with reimbursement for expenses incurred  
40 in the course of their participation. The members shall be

1 reimbursed for travel and other necessary expenses incurred in  
2 their performance of the duties of the council.

3 (q) No more than 10 percent of the total funds appropriated may  
4 be used for all aspects of the administration of this section.

5 (r) This section shall be implemented only to the extent that  
6 funding for its purposes is appropriated by the Legislature in the  
7 annual Budget Act.

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